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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,401

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Russell Edward Morris

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EXAMINER

JOHNSON, KEVIN M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,401	Applicant(s) MORRIS ET AL.	
	Examiner KEVIN JOHNSON	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,42-49 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,42-49 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 5/23/2011 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-8, 42-49 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims require a composition that includes a “pharmaceutically, nutraceutically or cosmetically-acceptable carrier” but it is not clear from the instant disclosure what are the requirements for a pharmaceutical, nutraceutical or cosmetic carrier. As a result it would not be possible for one of ordinary skill in the art at the time of the invention to determine what carriers meet the requirements of the instant claims. For the purposes of examination, the claims have been interpreted as requiring the presence of a carrier.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 6-8, 42, 43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Langmuir, 1993, 9, pp. 2337-2343) in view of Wu (US 5492883).

In regard to claims 1-3, 6-8 and 53, Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Cu-MFI type zeolite, where the Cu ions may be considered extra-framework cations (table I). The zeolite material is in the form of a powder (p. 2338, IR measurement). The material would be capable of releasing NO by displacement with moisture at room temperature because the zeolite material meets all other requirements of the instant claims. Zhang teaches that a self-supporting monolith may be formed from the powder by compressing the powder for 30 minutes (p. 2338, IR measurement), but fails to disclose that a binder is employed.

Wu discloses a method of combining a zeolite material and an organic binder, and then extruding the composition to form a monolithic structure (column 3, lines 50-62). An example of a useful organic binder disclosed by Wu is a polyvinylpyrrolidone (column 5, lines 59-60)

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a binder as disclosed by Wu in the formation of the monolith taught by Zhang. Such a modification would have been motivated by the teaching in Zhang that the zeolite material may be formed in to a monolith, and the disclosure by Wu of a method for the formation of a zeolite containing monolith incorporating a binder. The binder disclosed by Wu would constitute a carrier as required by the instant claims.

In regard to claim 42, Wu discloses that silica is an established binder for the production of zeolite materials (column 4, lines 21-36).

In regard to claim 43 and 44, the material disclosed by Zhang is dried prior to NO adsorption (page 2338, column 1).

7. Claims 1-3, 6, 43, 44, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (JP 08092051 A) in view of Zhang and Green et al. (US 5814666).

In regard to claims 1-3, 46 and 49, Yamamoto discloses a deodorizing cosmetic. The composition comprises an antimicrobial zeolite and a silicone carrier (abstract). The zeolite disclosed by Yamamoto does not meet the requirements of the instant claims.

Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Cu-MFI type zeolite, where the Cu ions may be considered extra-framework cations (table I). The zeolite material is in the form of a powder (p. 2338, IR measurement). The material would be capable of releasing NO by displacement with moisture at room temperature because the zeolite material meets all other requirements of the instant claims.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite disclosed by Zhang in the carrier containing deodorizing cosmetic composition disclosed by Yamamoto. Such a modification would have been motivated by the teaching in Yamamoto that the composition includes antimicrobial zeolites, and the disclosure in Green that materials capable of releasing nitric oxide

Art Unit: 1732

exhibit antimicrobial functionality and the disclosure in Zhang of zeolites have the capability to release adsorbed nitric oxide.

In regard to claim 6, Yamamoto discloses that the cosmetic may be in the form of a powder or stick.

In regard to claims 43 and 44, the material disclosed by Zhang is dried prior to NO adsorption (page 2338, column 1).

8. Claims 1-3, 45, 47, 48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 2000/64506 A1) in view of Zhang and Green.

In regard to claims 1-3, 45, 47, 48 and 53, Barry discloses a stent that incorporates an antimicrobial agent. The antimicrobial agent is preferably a zeolite that exhibits antimicrobial activity (page 3, lines 2-3). The zeolite may be incorporated in to the stent as part of a resin powder that is prayed on to the stent (page 7). The resin powder that the zeolite is incorporated in to meets the carrier and binder requirements of the instant claims. The zeolite employed by Barry does not meet the requirements of the instant claims.

Zhang discloses a zeolite that contains reversibly adsorbed NO (abstract). An exemplary embodiment of such a zeolite is a Cu-MFI type zeolite, where the Cu ions may be considered extra-framework cations (table I). The zeolite material is in the form of a powder (p. 2338, IR measurement). The material would be capable of releasing NO by displacement with moisture at room temperature because the zeolite material meets all other requirements of the instant claims.

Green discloses that compositions capable of releasing nitric oxide have an antimicrobial effect (column 4, lines 37-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the zeolite material disclosed by Zhang in the stent described by Barry. Such a modification would have been motivated by the teaching in Green that materials capable of releasing nitric oxide exhibit antimicrobial functionality, Zhang's disclosure of zeolites have the capability to release adsorbed nitric oxide and the teaching in Barry that zeolites with antimicrobial functionality may be beneficially included in stents.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang and Wu as applied to claim 1 above, and further in view of Rudolf et al. (Journal of Magnetic Resonance, 2002, 155, pp. 45-56).

In regard to claims 4 and 5, Zhang discloses that a variety of zeolite frameworks have the capacity to adsorb NO (table 1). The materials are formed by ion exchanging the Na form of zeolites, with Cu exhibiting a particular affinity for NO adsorption (p. 2337-38). Zhang fails to disclose a zeolite with the LTA framework as required by the instant claims.

Rudolf discloses a sodium exchanged type-A zeolite, Na-A, for use in the adsorption and desorption of NO. Zeolite-A has the LTA structure required by the instant claims.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the zeolite A disclosed by Rudolf for the MFI zeolites disclosed by

Zhang, resulting in a Cu-A zeolite material. Such a modification would have been motivated by the disclosure in Zhang that many zeolite frameworks are suitable for NO adsorption, that the Cu form of zeolites produced from the Na form exhibit particularly effective NO adsorption and the disclosure in Rudolf that zeolite A is capable of NO adsorption.

Response to Arguments

10. Applicant's arguments filed 5/23/2011 have been fully considered but they are not persuasive.

The argument that the requirement in the instant claims of “pharmaceutically, nutraceutically or cosmetically-acceptable carrier” is not indefinite is not persuasive. The applicant has referenced compilations of known materials useful as pharmaceutically, nutraceutically or cosmetically-acceptable carriers, but has not provided these materials. Additionally, it would appear from the applicant's description of these materials that, while they list known carriers of the type referred to by the claims, they do not seem to offer a definition of the characteristics that define a “pharmaceutically, nutraceutically or cosmetically-acceptable carrier.” As no definition or explanation of what properties are required of a “pharmaceutically, nutraceutically or cosmetically-acceptable carrier” has been provided, the instant claims are indefinite.

The argument that Zhang is not concerned with the chemical displacement of NO is not persuasive. The instant claims are directed to a composition, and the limitations in the instant claims related to chemical displacement of NO are directed to intended use. The composition suggested by Zhang and Wu is the same as the composition required

Art Unit: 1732

by the instant claims, and as a result would be expected to have the same capacity for chemical displacement of NO.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN JOHNSON whose telephone number is (571)270-3584. The examiner can normally be reached on Monday-Friday 9:00 AM to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Mayes can be reached on 571-272-1234. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KEVIN JOHNSON/
Examiner, Art Unit 1732

August 1, 2011

/Melvin Curtis Mayes/
Supervisory Patent Examiner, Art Unit 1732